

§ 124.32 APHIS action on petition.

(a) Within 90 days after APHIS receives a petition filed under § 124.30, the Under Secretary for Marketing and Regulatory Programs shall make a determination under paragraphs (b) or (c) of this section or under § 124.33 whether the applicant acted with due diligence during the regulatory review period. APHIS will publish its determination in the FEDERAL REGISTER together with factual and legal basis for the determination, notify PTO of the determination in writing, and send copies of the determination to PTO, the applicant, and the petitioner.

(b) APHIS may deny a due diligence petition without considering the merits of the petition if:

(1) The petition is not filed in accordance with § 124.30;

(2) The petition does not contain information or allegations upon which APHIS may reasonably determine that the applicant did not act with due diligence during the applicable regulatory review period; or

(3) The petition fails to allege a sufficient total amount of time during which the applicant did not exercise due diligence so that, even if the petition were granted, the petition would not affect the maximum patent term extension which the applicant is entitled to under 35 U.S.C. 156.

[59 FR 11369, Feb. 25, 1993, as amended at 64 FR 43045, Aug. 9, 1999]

§ 124.33 Standard of due diligence.

(a) In determining the due diligence of an applicant, APHIS will examine the facts and circumstances of the applicant's actions during the regulatory review period to determine whether the applicant exhibited the degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period. APHIS will take into consideration all relevant factors, such as the amount of time between the approval of an experimental use permit and licensure of the veterinary biological product.

(b) For purposes of this Part, the actions of the marketing applicant shall be imputed to the applicant for patent

term restoration. The actions of an agent, attorney, contractor, employee, licensee, or predecessor in interest of the marketing applicant shall be imputed to the applicant for patent term restoration.

Subpart E—Due Diligence Hearing

§ 124.40 Request for hearing.

(a) Any interested person may request, within 60 days beginning on the date of publication of a due diligence determination by APHIS in accordance with § 124.32, that APHIS conduct an informal hearing on the due diligence determination.

(b) The request for a hearing must:

(1) Be in writing;

(2) Contain the docket number of the FEDERAL REGISTER notice of APHIS's regulatory review period determination;

(3) Be delivered to the Director, Center for Veterinary Biologics, Licensing and Policy Development, 510 South 17th Street, Suite 104, Ames, IA 50010-8197.

(4) Contain a full statement of facts upon which the request for hearing is based;

(5) Contain the name, the address, and the principal place of business of the person requesting the hearing; and

(6) Contain a certification that the person requesting the hearing has served a true and complete copy of the request upon the petitioner of the due diligence determination and the applicant for patent term extension by certified or registered mail (return receipt requested) or by personal service.

(c) The request must state whether the requesting party seeks a hearing not later than 30 days after the date APHIS receives the request, or, at the request of the person making the request, not later than 60 days after such date.

[58 FR 11369, Feb. 25, 1993, as amended at 59 FR 67617, Dec. 30, 1994; 64 FR 43045, Aug. 9, 1999]

§ 124.41 Notice of hearing.

No later than ten days before the hearing, APHIS will notify the requesting party, the applicant, the petitioner, and any other interested person of the date, time, and location of the hearing.